REMARKS

This paper is being filed in order to amend the claims of the above-referenced application. No fees are believed to be due in connection with this filing, however, should any fees be necessary, the Commissioner is authorized to deduct the fees from our Deposit Account No. 13-2855. A duplicate copy of this paper is enclosed.

A. Status of Claims

Claims 1, 2, 4, 26, 28, 30-32, 39, 40, 42, 44, 51, and 63-73 are pending in the U.S. Application No. 09/485,512 and have been allowed by the Examiner. Upon allowance, *ex parte* prosecution was suspended and the instant application became involved in Patent Interference No. 105,358, in which the applicants were senior party and Reddy, the patentee of U.S. Patent No. 6,492,343 was the Junior party. A judgment in favor of the applicants has now been issued in that interference and the applicants present amendments to the claims and solicit a notice of allowance with respect to the amended claims. The amendments presented above are summarized as follows:

- Claims 1, 4, 28, 30, 31, 39, 44-50, 57-62, 70, 72, and 73 have been amended;
- Claims 2, 26 and 63-69 have been cancelled;
- Claims 26 has been cancelled and the limitations of claim 26 have been incorporated into amended claims 28 and 30;
- Claims 4, 44-50 and 57-62 have been amended to modify the antecedent basis of those claims so that the claims now depend from claim 28 or claim 30 as opposed to cancelled claim 2;
- Claims 51-56 and 71 are presented in the above claim list as previously allowed by the Examiner;

B. Background information from Patent Interference No. 105,358

A two-count Interference No. 105,358 was declared between the allowed claims of Johnson's '512 application and Reddy U.S. Patent No. 6,492,343. Count 1 of the Interference was:

> "A vector according to Claim 30 of U.S. Application 09/485,512 or Claim 21 of U.S. Patent No. 6,492,343."

Claim 30 of 09/485,512 depends from claim 2 of the application and recited:

> "A recombinant vector as claimed in claim 2 wherein said heterologous DNA is stably integrated into the adenovirus E3 region of the genome at map units from about 81 to about 84."

Claim 21 of U.S. patent 6,492,343, dependent on claim 13 of that patent, recited:

> "The recombinant PAV-3 vector according to claim 13 wherein the heterologous nucleotide sequence is inserted in the E3 region."

Thus, Count 1 of the interference was directed to a recombinant porcine adenovirus-3 vector which contained a heterologous DNA/nucleotide sequence inserted into the E3 region of the PAV-3 genome.

Count 2 of the interference was:

> "A vector according to Claim 28 of U.S. Application 09/485,512."

Claim 28 of the '512 application recited:

> 28. [currently amended] A recombinant vector as claimed in claim 2 wherein said heterologous DNA is stably integrated into the right hand end of the genome at map units from about 97 to about 99.5.

Thus, Count 2 of the interference was directed to a recombinant porcine adenovirus-3 vector which contained a heterologous DNA sequence inserted into the PAV-3 genome at map units from about 97 to about 99.5.

The interference culminated in an adverse judgment against Reddy with respect to both Count 1 and Count 2 (copy of Judgment attached as Exhibit A).

During the interference, Reddy filed three preliminary motions:

a. Reddy Substantive Motion 1 (to change the benefit accorded to Johnson for the contested subject matters of Count 1; attached as Exhibit B);

b. Reddy Substantive Motion 2 (for judgment based on unpatentability of all involved Johnson Claims for Failure to comply with 35 U.S.C. §112, paragraph 1; attached as Exhibit C)

c. Reddy Substantive Motion 3 (for judgment on grounds of indefiniteness 35 U.S.C. §112, paragraph 2; attached as Exhibit D).

In response to the above three motions, Johnson filed a responsive motion 2 in which Johnson requested the above amendments to the claims. As noted in the Judgment (Exhibit A), Reddy's Substantive Motion 1 was dismissed as moot in light of the adverse judgment entered against Reddy. The Board recommended that Johnson's response to Motions 2 and 3 be addressed in the '512 application once *ex parte* prosecution is resumed.

C. Johnson's General Comments in Response to Motions 2 and 3 filed by Reddy in Patent Interference No. 105,358

Reddy Substantive Motion 2 asserted that all of Johnson's claims were unpatentable for failing to comply with the enablement and written description requirements of 35 U.S.C. §112, first paragraph. Reddy's Substantive Motion 3 attacked the patentability of Johnson's claims based on indefiniteness under 35 U.S.C. §112, second paragraph.

In Substantive Motion 3, Reddy asserted that "Johnson's claims suffer from a fatal flaw: they are all refer to "map unit" ranges that are ambiguous at best, given the specification's contradictory guidance as to the size of the PAV3 genome." [Reddy Substantive Motion 3 at page 11]. Reddy Substantive Motion 3 also objected to the use of the term "from about . . . to about" in claims 28 and 30 [*Id.* at page 10]. Reddy Substantive Motion 3 did not argue that the Johnson claim term, "non-essential region," is indefinite *per se*, only that the term as applied to the map units recited in Johnson's involved claims does not otherwise save those claims from indefiniteness based on reference to map units. [Reddy

Substantive Motion 3, at page 11]. Moreover, Reddy Substantive Motion 3 did not argue that reference in the Johnson claims to "the E3 region" is indefinite.

In the above amendment, claims 1, 4, 28, 30, 31, 32, 39, 40, 42, 44-62, 70, 72, and 73 are amended and claims 2, 63, 65, 66, 67, 68, and 69 are cancelled. More particularly:

a. Claims 1, 31, 39, 70, 72, and 73 have been amended to remove recitation of mapping units 50-55, 55-65, 72-85. As a corollary amendment, Claims 63, 65, 66, 67, 68, and 69 have been canceled;

b. Claims 1, 31, 39, 70, 72 and 73 have been amended in order to remove recitation of mapping units 81-84 and to insert the term "the E3 region" therefore;

c. Johnson claims 28 and 30 are re-written in independent format by incorporating the applicable limitations of claim 2. As a corollary amendment, claim 2 has been canceled, and claims 4, 32, 44-62 have been amended to correct the antecedent basis of those claims so that the claims now depend from claim 28 or claim 30 as opposed to canceled claim 2;

d. Claim 26 has been cancelled and the limitations of claim 26 have been incorporated into amended claims 28 and 30; and

e. Claims 32, 40, 42 and 51-56 and 71 are as previously presented.

The amendment presented above is such that at least some of the written description/enablement grounds alleged for unpatentability in Reddy Substantive Motion 2 are mooted or "cured" and **all** grounds alleged for unpatentability in Reddy Substantive Motion 3 based on indefiniteness are likewise mooted or "cured." Briefly put, the requested narrowing amendments and cancellations preserve patentability of the claims, but eliminate all references to PAV3 genome "map units" except for one reference ("map units 97-99.5") which is separately defined in the Johnson '512 specification by reference to the DNA sequence in Figure 4. The requested amendments also eliminate use of the term, "from about...to about" in any claim.

D. Johnson's Specific Comments in Response to Motion 3 filed by Reddy in Patent Interference No. 105,358

Reddy's arguments in Substantive Motion 3 were based entirely on recitation of map units in the Johnson claims, and on the use of the term "from about . . . to about" in claims 28 and 30. As discussed further below, each of these arguments is rendered moot by the requested amendments.

1. Reddy's arguments relating to map units are rendered moot due to deletion of map units 50-55, 55-65, 72-85 and 81-84 from the claims and the fact that the DNA sequence of 97-99.5 is explicitly defined in Figure 4 of the '512 specification

In Substantive Motion 3, Reddy argued that the Johnson claims are fatally flawed because at the time the present application was filed the skilled person would not have known which sequences of the PAV3 genome corresponded to the map units recited in the claims of the '512 application [Reddy Motion 3, pages 6-9]. Upon entry of the requested amendments, only designated claims 28, 31, 71, 72 and 73 contain any reference to map units in the PAV3 genome identifying sites for DNA insertion. This reference is to "map units 97-99.5" which is independent of any consideration of genome size and is entirely defined in the '512 specification. More particularly, the right hand end of the PAV3 genome is defined in the specification as constituting "MU 97-99.5" and its DNA sequence is shown in Figure 4 which includes restriction endonuclease cleavage sites for DNA insertion such as the *SmaI* site used in the working examples. (Facts ¶ 4, 6). Claims 28, 31, 71, 72 and 73 are thus definite in their recitation of "map units 97-99.5" when viewed in light of the specification.

Claims 30, 31, 72 and 73 have been amended to remove recitation of map units 81-84 so as to refer only to "the E3 region." This term is used to characterize a DNA sequence that was known to those of skill in the art at the time the present application was filed, having previously been published in 1995 (*See* Reddy et al. *Virus Research* 36:97-106, 1995; attached as Exhibit E).

2. Reddy's arguments relating to the use of the term "from about ... to about" are rendered moot due to deletion of that term from claims 28 and 30

At page 10 of its Substantive Motion 3, Reddy objects to use of the term "from about . . .to about" in claims 28 and 30. The requested amendment of claims 28 and 30 deletes the questioned term, thereby rendering moot Reddy's objections.

Thus, the amendments made above render all of the arguments made in Reddy Substantive Motion 3 moot on the issue of alleged indefiniteness of the claims of the present application.

E. Johnson's Specific Comments in Response to Motion 2 filed by Reddy in Patent Interference No. 105,358

Moving now to Reddy Substantive Motion 2, that motion attacked the patentability of Johnson's claims alleging four separate arguments under 35 U.S.C 112, first paragraph for lack of enablement and/or written description. Briefly, these arguments were:

a) the '512 application does not describe or enable PAV3 incorporating foreign DNA at insertion sites 50-55, 55-65 or 72-85 (Section C of Reddy Motion 2);

b) the '512 application does not enable PAV3 incorporating foreign DNA at map units 97-99.5 (Section D of Reddy Motion 2);

c) the '512 application does not enable or describe PAV3 incorporating foreign DNA in the E3 region at map units 81 to 84 (Section E of Reddy Motion 2);

d) the '512 claims encompass replication defective recombinant PAV3 adenoviruses that are not described or enabled (Sections F and G of Reddy Motion 2).

Section C of Reddy Substantive Motion 2 (pages 5 through 7 of Exhibit C) attacks patentability of Johnson's claims 1-2, 4, 26, 31, 39-40, 42, 44-65, 67, 68-69 and 72-73 based exclusively on their reference to "MU 50-55, 55-65 or 72-85." These map unit references were incorporated into the claims by amendment following the Examiner's consideration of the arguments presented during ex parte prosecution and the assessment that the PAV3 gene sequences corresponding to those map units were available to those skilled in the art at the time the '512 application was filed.

Regardless of the fact that the Patent Office has previously allowed the claims with inclusion of these map units, in the amendments requested herein, no such map unit references appear in any Johnson claim. As such, arguments in Section C of Reddy's Substantive Motion 2 based on reference to "MU 50-55, 55-65 or 72-85" are mooted.

Turning now to Section D of Reddy Substantive Motion 2, it was argued by Reddy that "map units 97-99.5 encompass nucleotides that are essential to viral replication" (Reddy Substantive Motion 2, page 8). In support of this assertion, Reddy acknowledged that the '512 application discloses a non-essential region where insertions to be made are "regions at the right terminal end of the genome at map units 97-99.5 (Reddy Substantive Motion 2, statement of facts ¶38). Reddy further acknowledged that the specification further specified the area of insertion in Figure 4 which identifies the putative TATA site for the E4 promoter (Reddy Substantive Motion 2, statement of facts ¶39). However, Reddy's statement of facts then proceeded to note that because E4 is an essential region, it may be that an insertion downstream of the TATA could disrupt E4 expression and destroy the PAV3 vector's ability to replicate (Reddy Substantive Motion 2, statement of facts ¶ 42) and that to practice the full scope of these claims it would be necessary to provide a helper cell line capable of replacing the function of the disabled E4 genes. Reddy arrived at this interpretation by ignoring the definition of map units 97-99.5 provided in the Johnson application and instead looking to definitions in references that were published after the filing date of Johnson. Johnson respectfully disagrees with the conclusions reached in Reddy Substantive Motion 2.

Initially, Reddy appears to have ignored the fact that the Johnson application provides an explicit working example of a recombinant PAV3 vector in which a heterologous

DNA was inserted into a region which the Johnson application expressly defines as the region between map units 97 to 99.5. The '512 specification specifically addresses insertion of a gene into "the *SmaI* site of the right hand end (MU 97-99.5) of porcine adenovirus serotype 3..." [see specification, page 12 lines 21-22 and page 13 lines 20-21]. Nucleotides corresponding to the right hand end of the PAV3 genome are set out in Figure 4 of the '512 specification along with restriction endonuclease sites of interest for insertion of foreign DNA, including the *SmaI* site where insertion was actually made in the working examples. [See specification page 12 lines 24-31 and Figure 4].

The specification specifically provides a teaching of how to prepare recombinant PAV-3 vectors in a manner that is consistent with the enablement standard set forth in *In re Wands,* 858 F.2d 731, 742 (Fed. Cir. 1988), which looked to eight factors to provide a standard of reasonableness for determining whether a specification satisfies the enablement requirement for a claimed invention, namely: (1) quantity of experimentation necessary (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.

Looking to the final factor, the breadth of the claims, focuses the inquiry relating to the other factors. Claim 28, as amended above, states:

> A recombinant vector including a recombinant porcine adenovirus stably incorporating, and expressing heterologous DNA wherein said heterologous DNA is stably integrated into a non-essential region of the right hand end of the genome at map units from 97 to 99.5.

This claim expressly requires insertion "***a non-essential region*** of the right hand end of the genome ***at map units from 97 to 99.5***" These clear and explicit recitations in the claim debunk Reddy's notion that the skilled artisan "could" end up producing a vector in which the E4 expression may be disrupted. The claim expressly recites that the insertion should be in a non-essential region. Given this direction in the claim, there is no credible reason as to why the skilled artisan would insert downstream of the TATA region into a sight that ***might*** disrupt E4 expression. The claims of the present application concisely cover the subject

matter of the invention in a manner that is fully enabled by the specification, as can be seen from the application of the remaining *Wands* factors given below.

For the "quantity of experimentation needed," the Federal Circuit has stated that undue experimentation is "not merely quantitative," and that a considerable amount of experimentation is permissible. *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998). Thus, it is the amount of non-routine experimentation, not the total quantity of experimentation that is to be assessed when looking to whether enablement is met. In the present case, the inventors expressly showed the preparation of a recombinant PAV-3 adenovirus in which a heterologous DNA was inserted into the region at map units 97 to 99.5. Figure 4 shows a restriction enzyme site within the complete sequence between map units 97 to 99.5. Armed with the instructions provided by the Applicants in the present specification, it would be a matter of routine for one skilled in the art to insert heterologous DNA into the same site as taught in the specification. Moreover, at the time the instant application was filed, engineering of restriction sites into a known sequence also was a matter of routine laboratory practice. Given that Figure 4 of the specification explicitly sets forth the sequence of the region at map units 97 to 99.5, the skilled person need only turn to such routine laboratory practices to engineer further sites into the region for inserting heterologous DNA. Thus, application of the first of the *Wands* factors would point to a conclusion that the claims of the present invention are enabled.

The application of the second *Wands* factor, i.e., looking to the amount of guidance provided and the third *Wands* factor i.e., whether there are working examples in the specification also supports a conclusion of sufficient enablement in the specification. As noted above, the specification provides an explicit working example of how to make the recombinant vector and it also provides a teaching that the region at map units 97 to 99.5 is particularly preferred. The working examples in the specification form a recipe for the skilled artisan to follow in order to make and use the claimed recombinant vectors.

The present invention is directed to manipulation of a region of a genome whose sequence is expressly taught in the specification. Reddy noted that the technological field at issue in this application is recombinant porcine adenoviruses that are engineered to be

useful as vaccines (Reddy Substantive Motion 1, page 1). Therefore, the nature of the invention is in the biotechnology art and while this art is oftentimes asserted as being an unpredictable art, the level of skill of those practicing this art is high. Indeed, in the present case, Reddy's expert noted that the person of ordinary skill in this art would have had at least a Masters degree in biological sciences and/or a Bachelors degree with at least two years experience in adenoviruses and have been familiar with scientific and technical publications concerning animal adenoviruses and in particular porcine adenoviruses (See paragraph 9 of Spindler declaration, attached as Exhibit F).

To a skilled person, given the instruction specifically set forth in the specification to modify the PAV-3 vector, manipulating nucleotide sequences to insert heterologous DNA into the sequence would have been a matter of routine laboratory practice in light of the teachings of the specification. As noted in the Spindler declaration, such a person would have access to the prior art in this field. As Reddy noted, such a person had recognized adenoviruses as having potential to be recombined with foreign genes for the purposes of creating vaccines and as vectors for the delivery and expression of foreign DNA. (See Reddy Substantive Motion 1, pages 1-2). Prior to the present invention, those skilled in the art had used homologous recombination to generate recombinant human adenovirus vectors as described in, among others, Chartier et al., *J. Virol.*, 1996, 4805-4810 (attached as Exhibit G); Bett et al., *Proc. Natl Acad Sci.*, 91: 8802-8806, 1994 (attached as Exhibit H); Crouzet et al., *Proc. Natl Acad Sci.*, 94:1414-1419, 1997 (attached as Exhibit M); He et al., *Proc. Natl Acad Sci.*, 2509-2514, 1998 (attached as Exhibit I); Ketner et al. *Proc. Natl Acad Sci.*, 91:6186-6190, 1994 (attached as Exhibit J). Thus, the level of skill of those in the art was high and teachings in the prior art showed that it was possible to prepare recombinant human adenoviruses that could be used as vaccines. These facts when viewed in light of the teachings in the specification would support a finding that application of *Wands* factors 4, 5, 6 and 7 also would lead to a conclusion that the claims of the present invention are enabled.

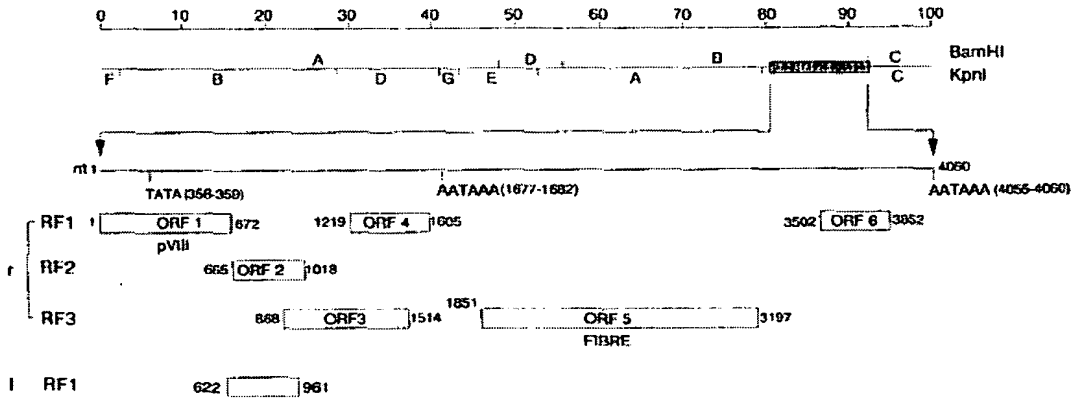
In view of the above discussion, the applicants maintain the '512 application fully enables claims directed to PAV3 that has foreign DNA incorporated at map units 97-99.5.

In Section E of Substantive Motion 2, Reddy argued that the '512 specification does not describe or enable integration of foreign DNA into the PAV-3 E3 region because the specification describes E3 as overlapping L4 but E3 does not overlap L4 rather it overlaps L5 and there is no portion of E3 after the polyadenylation signal of L5. Secondly, Reddy argued that the '512 application does not describe or enable integration of foreign DNA "at map units from about 81 to 84."

As noted above, Applicants removed all reference to "map units 81 to 84" from the claims in response to Reddy's arguments relating to definiteness of the claims. This amendment also addresses the second argument that Reddy posited with respect to lack of written description and enablement of insertion at map units 81 to 84. The broadest of the relevant claims in this case is claim 30, which recites:

> A recombinant vector including a recombinant porcine adenovirus stably incorporating, and expressing heterologous DNA wherein said heterologous DNA is stably integrated into a non-essential region of the adenovirus E3 region of the genome

Again, this claim and claims dependent on this claim are not broad, but rather concisely cover specific subject matter of the invention in a manner that is fully enabled by the specification. The sequence of the E3 region of PAV-3 was published in 1995 by Reddy et al. (*Virus Research* 36:97-106; Exhibit E). Figure 1 of that paper showing the physical map of PAV-3 restriction enzymes *Bam*HI and *Kpn*I is reproduced below:



In that paper, Reddy et al. noted that the E3 region lies between the genes coding for the precursor protein pVIII and the fibre protein of the L4 and L5 regions of the genome respectively and that as such, "the E3 region of PAV-3 would be located between ORF 1 and ORF 5." Therefore, in the above Figure, the coding sequences for ORF 2, ORF 3 and ORF 4, and the nucleotides between the end of ORF 4 and the beginning of ORF 5 constitute the PAV-3 E3 region. In Reddy et al. Figure 3, the entire sequence of the between map units 79.5 and 92 is also is shown.

From Reddy et al. 1995 the skilled artisan could readily determine that:

- ORF 1 (pVIII, also referred to as L4) is encoded by nucleotides 1-672 of Figure 3;
- ORF 2 is encoded by nucleotides 665-1018;
- ORF 3 is encoded by nucleotides 888 to 1514;
- ORF 4 is encoded by nucleotides 1219 to 1605;
- ORF 5 (Fibre, also referred to as L5) begins at nucleotide 1851;
- There is a non-coding region between the end of ORF 4 and the beginning of ORF 5 (i.e., the nucleotides between 1605 and 1851;
- There is a polyadenylation site located at nucleotides 1677-1682 in the non-coding region between the end of ORF 4 and the start of ORF 5; and
- The PAV3 E3 region begins at nucleotide 665 (start of ORF 2) and ends at nucleotide 1851.

In view of the teaching of Reddy et al 1995 alone, the skilled person would have been well aware of the nucleotide sequence the entire PAV-3 E3 region as well as other ORFs near the E3 region. Given that the present application expressly directed the skilled person to insert into the E3 region, and the fact that the sequence of the PAV-3 E3 region was well known prior to the filing date of the present application, there was no need to provide a written description of that sequence in the specification. The skilled artisan would have known what was intended by the E3 region of PAV-3 and would have readily referred to the published

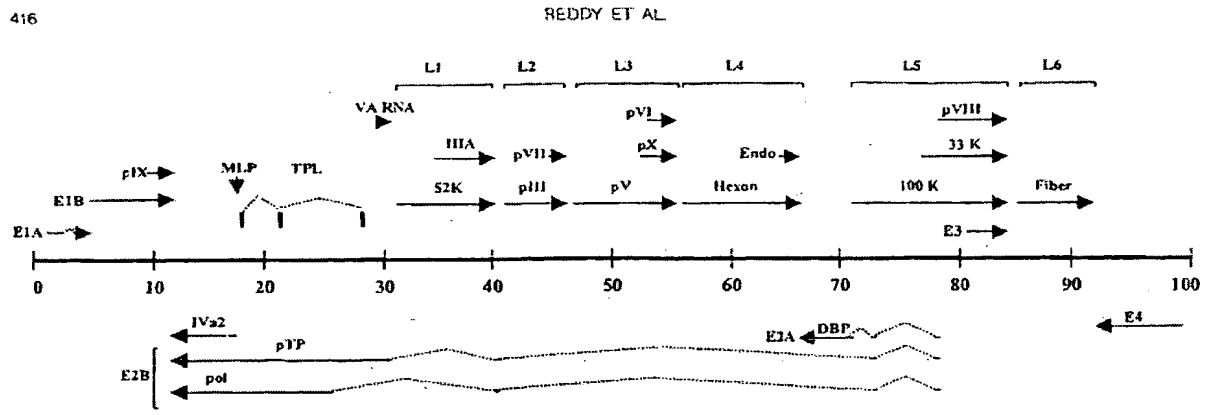
sequence in the literature in preparing the PAV-3 vectors containing insertions in the E3 region.

The argument that the skilled person would not have understood where in E3 to insert the heterologous DNA is specious. At the time that the instant application was filed the Reddy et al. 1995 paper (page 104, relevant sentences reproduced below) expressly noted that pVIII and Fibre were "L4 and L5 regions of the genome, respectively."

In yet another Reddy paper (Reddy et al., Virus Research 43:99-109, 1996; attached as Exhibit K) that was published prior to the filing of the instant application, the organization of the PAV-3 genome is again discussed and it is noted that in PAV-3 as with other adenoviruses, the E3 region lies between the genes coding for the precursor protein pVIII and the fiber protein of the L-4 and L-5 regions of the genome respectively (see page 107, second paragraph under discussion).

Thus, contrary to the assertions that Reddy makes in its Substantive Motion 2, Reddy's own publications show that at the time the instant application was filed the skilled person readily understood that pVIII was the L4 region of the genome and the fiber protein was encoded by the L5 region of the PAV-3 genome. Bearing that understanding in mind, one returns to the teachings of the specification which state that a possible insertion site could be after the polyadenylation signal of L4. As can be seen from the Figures 1 and 2 in Reddy et al. 1995, there is only one polyadenylation signal that is associated with the E3 region, it is located at nucleotides 1677-1682. After that polyadenylation signal, and before the start of the L5, fiber-encoding region, there is clearly a stretch of a non-coding region spanning nucleotides 1683-1851 as shown by Reddy's own publications. It is into this region that the '512 specification suggests that the insertion be made.

Reddy's statement that "E3 does not actually overlap L4 in PAV3; rather it overlaps with L5" (Reddy Motion 2, Section E, page 10) is a misnomer that arose out of Reddy *sua sponte* **redefining** the regions of the PAV-3 genome **after** the present application was filed. More specifically, in 1998 Reddy et al. published a revised genome map of PAV-3 (Virology 251(2):414-426, 1998; attached as Exhibit L). At page 420 of that paper, Reddy presented the following map:



From the above map, it is clear that what Reddy redefined as L5 in 1998 was a region of the genome which included the coding region for pVIII and what Reddy redefined as L6 in 1998 was the region of the genome that included the coding region for fibre. Thus, prior to 1998 Reddy referred to pVIII as being in L4, after 1998 Reddy referred to pVIII as being in L5. Regardless of whatever confusion the change in nomenclature may have created after the filing of the present application, the skilled person reviewing the teachings of the present specification and the teachings of Reddy et al. 1995 and 1996 would easily have understood that Johnson was using "L4" consistent with the nomenclature at the time of filing. And the skilled person would have understood that at the time of filing L4 equated to the region that encoded pVIII. Hence, Reddy's statement that it is impossible to make an insertion into E3 after the polyadenylation site is factually incorrect.

There would be very little experimentation required to prepare recombinant vectors that had incorporated into the E3 region once the teachings of the specification had been provided to one skilled in the art. Indeed, referring to the '512 application as filed particularly at pages 13-14 and the Figure 15, the skilled person will again find an express teaching on insertions into the *SnaBI/BsrGI* site within the E3 region of the PAV3 genome. Moreover, as further evidence of the fact that the teachings of the '512 application were sufficient to enable one to prepare a recombinant PAV-3 vector, one need only look to U.S. patent 6,492,343, the Reddy patent involved in Interference No. 105,358. In example 5 of the Reddy patent, Reddy shows incorporation of a heterologous nucleotide sequence into the *SnaBI* site of the E3 region. That site is **the very same site** that the '512 application guides the skilled person to use as a suitable site for insertion.

Finally, in Sections F and G of its Motion 2, Reddy argued that nearly all of Johnson's claims cover insertions into regions of PAV3 regardless of whether the region is essential or non-essential. These arguments are rendered moot by the amendments above which provide that the insertions are into non-essential regions of specific regions of the PAV-3 genome.

In view of the above, Applicants believe the '512 application provides full description and enablement for the scope of the claims directed to PAV-3 vectors incorporating foreign DNA into non-essential regions selected from the E3 region of PAV-3 or the region at map units 97 to 99.5.

F. Conclusion

In conclusion, the claims as presented herein are definite, fully described and fully enabled in the '512 application and the arguments presented in Reddy Substantive Motion 2 and Reddy Substantive Motion 3 cannot be used to defeat the patentability of the claims as amended herein.

Applicants respectfully request an early allowance of the application. If there are any questions regarding this submission the Examiner is invited to contact the undersigned representative.

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Respectfully submitted,

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